

III. Remarks**A. Rejection under 35 U.S.C. § 112****1. 35 U.S.C. § 112, ¶1 Rejection/Interview Summary**

The Action rejects claims 1, 6-10, and 12-23 as failing to comply with the written description requirement. Specifically, the Action states that it is not clear whether the following limitation is supported by the specification: "said X-ray picture resulting from x-raying said artificial reference specimen disposed in such a position that said picture of said artificial reference specimen is positioned beside said picture of said mandible in said X-ray picture."

The undersigned and the Examiner conducted a telephone interview on February 2, 2011 to discuss this rejection. The undersigned believes that an agreement was reached that this limitation is fully supported in the specification. As discussed during the interview, this limitation is fully supported by, for example, FIGS. 2-5 and the description found at Paragraphs 25 and 26 of the application. The undersigned confirmed that the aluminum block 36 shown in these figures and described in the specification is an embodiment of an artificial reference specimen as claimed. FIG. 2 illustrates an X-ray film having a picture resulting from the reference specimen (i.e., aluminum block 36) being positioned with respect to the subject's mandible, such that a picture of the reference specimen (shown as reference bar 36) is positioned beside the picture of the mandible in the X-ray. FIG. 3 illustrates an embodiment of the artificial reference specimen, specifically a stepped aluminum block. FIG. 4 shows the stepped aluminum block 36 adhered to a photograph surface 52 of an X-ray film 26. Finally, FIG. 5 illustrates the positioning of the X-ray film 26, and thus also the aluminum block 36, in the mouth of the subject so that the reference specimen 36 can be photographed with the mandible, which produces the combined picture of FIG. 2. Applicants respectfully submit that the foregoing citations fully support the limitation "said X-ray picture resulting from x-raying said artificial reference specimen disposed in such a position that said picture of said artificial reference specimen is positioned beside said picture of said mandible in said X-ray picture." Reconsideration and withdrawal of this rejection are respectfully requested.

2. 35 U.S.C. § 112, ¶2 Rejection

The Action rejects claim 13 as being indefinite for lacking antecedent basis for the limitation "said standard average" and "said standard deviation". Claim 13 has been amended to be consistent with the language used for these features in claim 12 from which it depends, namely "said preset standard average" and "said preset standard deviation". Reconsideration and withdrawal of the rejection are respectfully requested.

B. Claim Rejection under 35 U.S.C. § 103

1. Claims 1, 6-10 and 21-23

The Action rejects claims 1, 6-10 and 21-23 as being obvious from Choel et al. ("Trabecular alveolar bone in the human mandible: A dual energy x-ray absorptiometry study") in view of U.S. Published Patent Application No. 2001/0021269 to Inoue. The Action finds that Choel et al. teaches all of the features of independent claim 1 except for the recited "correcting means", for which the Examiner cites to Inoue. Reconsideration and withdrawal of this rejection are respectfully requested in view of the following arguments.

According to claim 1, the X-ray picture contains a picture of a mandible (i.e., the object to be examined) and a picture of an artificial reference specimen, which separate from and positioned with respect to the mandible. The artificial reference specimen is positioned such that the picture of the artificial reference specimen in the X-ray picture appears beside the picture of the mandible. The gradation of a particular portion of the picture of the artificial reference specimen in the X-ray picture is detected by detecting means. The gradation of the entire X-ray picture is then corrected by correcting means in such a manner that the gradation of the particular portion of the artificial reference specimen as detected by the detecting means complies with a preset standard value. Evaluating means evaluates a bone mineral density from the corrected gradation of a particular region of the picture of the mandible in the gradation-corrected X-ray picture, or, more specifically, from the corrected gradation of a region corresponding to an alveolar bone portion around the first premolar.

According to the invention of claim 1, an artificial reference specimen is used to facilitate quantitative evaluation of bone mineral density. The "artificial" reference specimen is used because its properties, such as material, a shape and/or dimensions, are constant and known. The gradation of an X-ray picture of a mandible (or any other object) may vary depending on various conditions including an x-raying condition. So, in order to make it possible to quantitatively evaluate the bone mineral density of a whole body from the gradation of such X-ray picture of a mandible, it is necessary to correct or normalize the gradation of the entire X-ray picture (or, more specifically, the gradation of at least a particular region of the picture of the mandible subject to the evaluation) in relation to a predetermined reference provided by the artificial reference specimen.

The Examiner cites to FIGS. 1 and 2 of Choel et al., and to the section "Chapter-Material and Methods: Ex vivo materials, page 365" for support as disclosing the claimed limitations of the X-ray picture containing a picture of an artificial reference specimen disposed beside a picture of the mandible where the X-ray picture results from x-raying the artificial reference specimen disposed in such a position that the picture of said artificial reference specimen is positioned beside the picture of said mandible in the X-ray picture. Applicant respectfully disagrees.

First, the Examiner states, "The author discloses that three regions of interest- G, R1 and R2 were delineated from the three specimens- Incisal specimen (IS), premolar specimen (PS) and molar specimen (MS), by the x-ray." However, these "three regions of interest- G, R1 and R2" referred to by Choel et al. are the particular regions of the actual specimens that are subject to examination, not a particular portion of an artificial reference specimen subjected to detection by the detecting means recited in claim 1 of the present application. Put another way, the three regions of interest – G, R1 and R2 – correspond to the particular regions of a mandible recited in claim 1 that are being evaluated, not to an artificial reference specimen that is positioned with respect to the mandible and then used in correcting the gradation of a combined X-ray picture of the mandible and the so-positioned artificial reference specimen.

Simply, Choel et al. operates in a manner that is fundamentally different than the operation of the claimed evaluation system. Choel et al. produces an X-ray picture of the test subject alone (called a "specimen" by Choel et al.), which is a slice of a cadaver jaw. The technique described in Choel et al. identifies regions of interest (shown by delineated boxes in FIG. 2) within the X-ray picture of the cut specimen. The specimens, being cut from the cadaver jaw, include the mandibular bone as a part of the specimens. That is, the mandibular bone is integral to the specimen. Choel et al. does not teach or suggest the use of a separate reference specimen (artificial or otherwise) that can be disposed/positioned beside the mandible as claimed to result in a combined X-ray picture of a test subject (i.e., the alveolar bone portion around a first premolar of a mandible) and the separate artificial reference specimen (which is not a part of the test subject but positioned with respect to it). To modify Choel et al. to provide a reference specimen, and particularly an artificial reference specimen, in addition to the cadaver specimen under test amounts to improper hindsight reconstruction of Applicants' invention. There is simply no teaching or suggestion in Choel et al., or the art of record, to do this.

Moreover, Choel et al. confirm that the researchers had no *a priori* knowledge of the characteristics (e.g., density) of their subject specimens. See Choel et al., at 365 ("No information was available concerning the osteoporosis status of these subjects."). There is certainly no teaching or suggestion from this disclosure to provide an artificial reference specimen, such as the aluminum block and/or stepped structure, by way of example, which has known characteristics along with the test subject that has unknown density as claimed.

Second, not only are the "ex vivo material" of Choel et al. not a "reference specimen" separate from the mandible under test and capable of being positioned with respect to the mandible, one of ordinary skill in the art in the art would not consider these "ex vivo materials" of Choel et al. to be "artificial." The specimens used by Choel et al. are organic, taken from fresh human cadavers, meaning they were once living tissue and thus not "artificial" in any sense (i.e., made by humans and not naturally produced). See Choel et al., at 365 ("The material consisted of 63 mandibular bone specimens cut from 21 fresh cadavers . . ."). Therefore, Choel et al. does not teach the use of an "artificial reference specimen" as claimed.

Third, one of ordinary skill in the art would not substitute an artificial reference specimen as claimed in claim 1 for Choel's organic specimen of irregular characteristics and structure and unknown density as suggested by the Action. It should be remembered that Choel et al.'s specimen is a slice of the mandible and is the actual object under test. All regions of interest are present in the slice. Substituting an artificial reference specimen as suggested by the Action would remove the actual specimen being tested and serve no purpose. Such a substitution makes no sense.

Finally, turning to the combination of Choel et al. and Inoue, the Action concedes that Choel et al. does not disclose the claimed "correcting means". But the Examiner relies on the combination of Choel and Inoue for providing a bone mineral density evaluation system having this feature. Inoue discloses an image processing apparatus which utilizes histogram equalizing processing to make an X-ray picture of a specific field of a human body more easily observable by an observer (i.e., more human readable) (see Paragraphs [0046]-[0057] and [0067] and [0077]-[0078]). The invention of Inoue has no relation to quantitatively evaluating bone mineral density of an entire human body from the gradation of an X-ray picture of a mandible of that human. One of ordinary skill in the art would not look to techniques for making an X-ray image more observable to a human observer in correcting X-ray images so that they are usable by bone evaluation means for evaluating bone mineral density.

Moreover, combining Inoue with Choel et al. would be a more human readable X-ray picture of a mandible that is subject to examination. It may be possible to evaluate, through sense, or qualitatively, the bone mineral density from such X-ray picture of a mandible, but it is not possible to make quantitative evaluation of the bone mineral density by the human eye. Correction for making an X-ray picture more human readable as taught by Inoue does not result in an X-ray picture corrected with respect to a preset standard value as claimed such that bone mineral density can be qualitatively determined by an evaluation means. Therefore, not only would one of ordinary skill in the art not look modify the teachings of Choel et al. based on techniques for making X-ray image more human readable, but the resultant combination would

not provide the claimed correcting means for correcting the gradation to comply with a preset standard value appropriate for bone mineral density evaluations.

For at least these reasons, Applicant submits that claim 1 is not obvious from combination of Choel et al. and/or Inoue, and is in allowable condition. Claims 6-10 and 21-23 depend from Claim 1 are, therefore, also in allowable form.

Applicants submit that claims 21-23 are also independently allowable over the cited combination of references. These claims recite that the artificial reference specimen is an aluminum block, has a stepped structure or both. In rejecting these claims the Examiner argues that it would have been a matter of design choice to a person of ordinary skill in the art to use an aluminum block or a stepped structure for the Ex vivo materials of Choel et al. because Applicant has not disclosed that the artificial reference specimen being an aluminum block, or a stepped structure or both provides an advantage, is used for a particular purpose or solves a stated problem. Applicant respectfully disagrees. First, as noted above, it would make no sense to substitute an artificial reference specimen for Choel's ex vivo materials because Choel's ex vivo materials include the actual area of interest to Choel et al. Moreover, Choel et al.'s technique does not even use a reference specimen that is positioned and X-rayed with a region of interest of a mandible bone in the first place. So, one of ordinary skill would not find it obvious at all to provide a reference specimen, let alone an artificial aluminum block, an artificial stepped structure or an artificial stepped aluminum block.

Second, contrary to the Examiner's assertions, the recited structures of these dependent claims *do* provide an advantage, are used for a particular purpose and do solve a stated problem. As described in the specification, a picture of a mandible and a picture of the specimen are taken, being juxtaposed on a single X-ray film. The density, i.e. darkness or lightness, of the specimen picture is detected by the detecting means, and the density of the X-ray picture or, more specifically, density of the picture of the mandible, is modified by the modifying means in such a manner that the result of detection by the detecting means matches a reference value. Using a reference specimen with known, constant characteristics, such as material and shape, allows for

the density of the picture of a given specimen to be modified to match the reference value, so that the density of the picture on the X-ray film can be modified with reference to the constant reference value, from which the bone mineral density is evaluated. With the example of an aluminum block 36 having a staircase shape, the reference bar 36 that appears on the X-ray picture has a density that varies along its length corresponding to the thickness or height of each step. (See, e.g., Pars. 25-28). Specifically, since a smaller thickness portion has a higher transmissivity to X-rays, the picture is darker, whereas a larger thickness portion has a lower transmissivity to X-rays, so that its picture is lighter. (See id.) The use of this reference specimen of known characteristics across multiple X-rays of a patient taken on different days facilitates the consistent determinations of the patient's bone mineral density. (See, e.g., Par. 28; FIGS. 6-17).

For at least these reasons, Applicants submit that claims 21-23 are independently allowable over the cited combination of references.

2. Claims 12-20

The Action rejects claims 12-14 and 16-20 as being obvious from Choel et al. in view of Kim. The Action rejects claim 15 as being obvious from Choel et al. in view of Kim and in further view of Inoue.

Independent claim 12 is allowable over the cited combination for the reasons analogous to those discussed above in connection with claim 1. That is, Choel et al. does not teach or suggest the use of an artificial reference specimen as claimed, nor employing such an artificial reference specimen as an index for use in correcting the gradation of an X-ray image.

Further, the Examiner concedes that Choel et al. does not disclose the claimed detecting means or the correcting means of claim 12. The Examiner relies on Kim for providing these features and finds that it would have been obvious to combine Choel et al. and Kim. Kim's invention relates to image quality enhancement. But Kim neither discloses nor suggests use of an index for use in gradation correction as claimed, like the artificial reference specimen as

recited in the amended Claim 12. Application of Kim's contrast enhancer, on which the Examiner relies in the Action, would simply enhance the picture quality of Choel et al.'s X-ray picture of a mandible under examination. But the enhanced image would not be an image corrected to comply with a preset standard average and a preset standard deviation as claimed that relates to gradations preset for evaluating bone mineral density. Processing an image for better human evaluation is not the claimed correction of gradation to preset standard average and standard deviation that are preset for performing qualitative bone mineral density evaluations by machine, not humans. Therefore, not only would one of ordinary skill in the art not look to incorporate Kim's qualitative image improvement techniques into Choel et al., but the combination would not result in the claimed "correcting means for correcting the gradation of said X-ray picture so as to make the-average and the deviation as detected by said detecting means comply with a preset standard average and a preset standard deviation."

Applicant respectfully submits that claim 12 and claims 13-20, which depend from claim 12, are not obvious from and are allowable over the cited references.

Moreover, for reasons analogous to those discussed above in connection with claims 21-23, Applicant submits that dependent claim 18-20 are independently allowable over the cited combination of references.

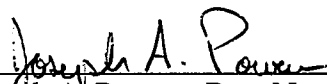
IV. Conclusion

In view of the foregoing remarks and amendments, Applicant submits that this application is in condition for allowance at an early date, which action is earnestly solicited.

The Commissioner for Patents is hereby authorized to charge any additional fees or credit any excess payment that may be associated with this communication to deposit account **04-1679**.

Respectfully submitted,

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